

Scientific & Medical Accountability Standards Working Group

About the Standards Working Group

The Scientific and Medical Accountability Standards Working Group makes recommendations to the 29-member Independent Citizens' Oversight Committee that governs the Proposition 71-funded California Institute for Regenerative Medicine on scientific, medical and ethical standards pertaining to stem cell research. The Working Group makes recommendations to the ICOC on compliance of adopted standards, as well as on modifications to standards.

Standards working group meeting agendas and transcripts are available in the meeting archives.

- Standards Working Group Members [pdf updated 9/2014]
- Standards Working Group Roles and Responsibilities
- Standards Working Group Meeting Procedures
- Standards Working Group Bylaws
- Conflict of Interest Policy for Standards Working Group [pdf]

Standards Working Group Recommendations

The ICOC has adopted policies recommended by the Standards Working group. These are now part of CIRM's formal regulations. The group has also created guidance documents to help CIRM grantees interpret the formal regulations.

- Formal regulations
- Reformatted Medical and Ethical Standards Regulations (unofficial) [pdf]
- Guidance documents
- Draft Recommendations on Human Gene Editing [pdf] (updated 6/8/16)
 - FINAL Informed Consent Consideration for Embryo Genome Editing Studies

CIRM Reports

CIRM holds workshops and meetings to explore, in-depth, scientific and policy issues within the field of stem cell research and regenerative medicine. Reports summarizing those workshops are available within a few months of each event.

- See all workshop reports

CIRM acceptably derived stem cell lines

Title 17 California Code of Regulations Section 100080 identifies criteria for the use of stem cell lines in CIRM funded research. Acceptable hESC lines include:

Lines previously approved by NIH [pdf] prior to March 2009: All listed lines are eligible for use in CIRM-funded research.
Lines listed on the NIH Human Embryonic Stem Cell Registry: All listed line are eligible for use in CIRM-funded research.
Lines deposited in the UK Stem Cell Bank: All listed lines are eligible for use in CIRM-funded research.
Lines derived with CIRM funding: All lines certified to be derived in accordance with CIRM regulations.

Stem cell lines certification or exemption

Use the form below to certify a stem cell lines has been derived in accordance with the CIRM regulations. Submit a form to include a line on our list of certified lines approved for use in CIRM-funded research.

- CIRM Pluripotent Stem Cell Line Certification Form [pdf]

Title 17 California Code of Regulations Section 100081 provides is an exemption process for lines derived prior to November 22, 2006. To be granted an exemption, the petition below must be submitted to CIRM.

- Exemption Petition Form for Lines Derived Prior to November 22, 2006 [pdf]

Publications by CIRM Staff

CIRM staff has worked in collaboration with members of the Standards Working Group and other scholars to publish on topics relating to medical and ethical standards. These publications do not necessarily represent CIRM policy. Rather they are intended to support ongoing consideration of ethical, legal, and policy considerations for stem cell science.

- Use of hESC Lines by CIRM Grantees: The Value of Embryonic Stem Cell Research Oversight (ESCRO) Committees *Journal of Stem Cell Research & Policy*
- Clinical Trials for Stem Cell Therapies [pdf]
- The Promise on Hold: The Impact of the NIH Stem Cell Funding Freeze [pdf]
- Policy Harmonization Through Collaboration: The Interstate Alliance on Stem Cell Research [pdf]
- Stem Cell Research: A Platform for Science-Policy Innovation [pdf]
- Governance of Stem Cell Science: Multiple Models & Similar Outcomes
- Proposed Oocyte Donation Guidelines for Stem Cell Research *Fertility and Sterility* [pdf]
- Harmonizing Standards and Coding for hESC Research *Cell Stem Cell* 3/02/08 [pdf]
- Similarities and Differences Among Stem Cell Research Policies: Opportunities for Policymakers, Patients, and Researchers *Medical Research Law & Policy* 11/05/2008 [pdf]
- Responsible Oversight of Human Stem Cell Research: The California Institute for Regenerative Medicine's Medical and Ethical Standards *PLoS Medicine* 5/07 [pdf]

Additional Resources for Stem Cell Policy

- California Department of Public Health Human Stem Cell Research Program
- International Society for Stem Cell Research
- Interstate Alliance on Stem Cell Research
- National Academies
- NIH Guidelines for Human Stem Cell Research [pdf]
- NIH hESC Registration Page

Source URL: <http://www.cirm.ca.gov/board-and-meetings/scientific-medical-accountability-standards-working-group>